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10/540,077	11/22/2005	Ulrich J. Pfeiffer	PFEIFFER ET AL -4 PCT	2638
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COLLARD & ROE, P.C. 1077 NORTHERN BOULEVARD ROSLYN, NY 11576			EXAMINER VU, QUYNH-NHU HOANG	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,077	Applicant(s) PFEIFFER ET AL.	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7-11 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 7-11 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Amendment filed on 3/20/08 has been entered.

Claims 1, 5, 7-11, and 14-16 are present for examination.

Claims 2-4, 6 and 12-13 are cancelled.

Applicant's arguments filed on (date) have been fully considered but are not persuasive.

Therefore, claims 1, 5, 7-11 and 14-16 are rejected in the new ground rejections as set below.

Oath/Declaration

The Oath/Declaration has been withdrawn based on the remark filed on 3/20/08.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 5,380,276) in view of Sima'n (US 5,968,009).

Miller discloses a catheter having a catheter body 10, the interior of which form a first catheter lumen 6 which can be served to accommodate a guide wire, having at least one partition disposed in the interior, which divides of at least one further catheter lumen 5 in the interior, wherein the catheter body 10 has a tubular outer wall, and the further catheter lumen 5 is disposed in such a manner that it has a wall section that is part of the tubular outer wall; the partition 8 runs in arc shaped over at least one section

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(claim 3); the arc-shaped partition 8 has a convex side that faces the first catheter lumen 6, and a concave side that faces the further catheter lumen 5; the cross-sectional area of the first catheter lumen has a round sickle shaped (claim 5); the cross-sectional area of the further catheter lumen is round; the catheter body is made from polyurethane (claims 14-15).

Miller does not specifically disclose the quotient of the cross-sectional area of the first catheter lumen F1 and the cross-sectional area of the further catheter lumen F2 is greater than the square of the quotients of the width of the first catheter lumen D1 and the width of the further catheter lumen D2, in the other words, $F1/F2 > (D1/D2)^2$.

Sima'n discloses, special in Fig. 3, the kink resistance tubing is increased by making the radius of the first lumen portion of the interior wall less than the radius of the second lumen portion to thereby provide a tubular having varying thickness wherein the thickness of the tubular wall adjacent to the first lumen is greater than the thickness of the tubular wall adjacent to the second lumen (see abstract or col. 2, line 64-col. 3, line 13). Since the varying thickness of the tubular wall will be effect and changing the size of the cross section area and the diameter of the lumen also. Therefore, given teaching of Sima'n will meet the formula that applicant discloses $F1/F2 > (D1/D2)^2$.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Miller with varying the thickness of wall, as taught by Sima'n, for the benefit of increasing kink resistance.

Regarding claims 16, Miller in view of Sima'n disclose the claimed invention except the guide wire has a diameter that amounts to 65% to 95% of the distance between the partition and the outer wall. It would have been obvious to one of ordinary skill in the art at the time the invention was made the diameter ranges from 65% to 95%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller in view of Sima'n and further in view of Currier et al. (US 2004/0015138).

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Regarding claims 7-8 and 11, Miller in view of Sima'n discloses the invention substantially as claimed. Miller in view of Sima'n do not disclose a temperature sensor is disposed in the other catheter lumen and disposed in the vicinity of the catheter tip.

Currier discloses a similar catheter device comprising a lumen 116 that receives sensors, wherein the sensors 102 can be used fiber-optics, temperature sensor, ect... (para 0061).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Miller in view of Sima'n with a temperature sensor, as taught by Currier, in order to calibrate the temperature or measure the temperature of the fluid flow in the lumen.

Regarding claims 9-10, Miller in view of Sima'n and further in view of Currier discloses the claimed invention except for the cross-sectional area of the temperature sensor fills the cross-sectional area of the further catheter lumen by at least four-fifths; wherein the cross sectional area of the temperature sensor fills the cross sectional area of the further catheter lumen completely. It would have been an obvious matter of design choice to make the size as forth-fifth or the temperature sensor filled in completely of cross sectional area of the catheter lumen, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

Response to Arguments

Applicant's arguments with respect to claims 1, 5, 7-11, 14-16 have been considered but are moot in view of the new ground(s) of rejection.

1. Applicant argues that Miller fails to disclose the cross sectional areas of both lumens of the catheter are approximately equal.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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Furthermore, Miller fails to disclose the dimensions of catheter lumen with unequal cross-sectional area. However, Sima'n teaches the benefits of dimension of catheter lumen with unequal cross-sectional area for increasing the kinking resistance as discussed above rejections, also see col. 3, lines 1-13).

2. Applicant argues that Sima'n focuses on catheters with about equal size lumens in col. 2, line 5.

Sima'n discloses in Fig. 1, one embodiment cover with the two lumens almost equal size. However, Siman' further discloses another embodiment where is the two lumens are different size, such as Figs. 3-4.

3. Applicant argues that Sima'n fails to disclose or suggest providing one of the lumens with a round shape.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Furthermore, the limitation one of the lumens with a round shape has been fully covered by reference of Miller. See rejection above.

4. Applicant argues that Sima'n fails to discloses or suggest the formula: $F1/F2 > (D1/D2)^2$.

In response, Applicant does not provide any evidences such as dimension of cross sectional area or diameter of two lumens to provide the formula above. Applicant only disclosure that the $F1 > F2$. Similarly, Sima'n clearly discloses that $F1$ (cross section area of lumen 232 of Fig. 3 or lumen 332 or 324 of Fig. 4) is greater than $F2$ (cross section area of lumen 230 of Fig. 3, or lumen 330 of Fig. 4). Furthermore, Sima'n discloses that the increased thickness in lumen wall along the first lumen (222 or 322) portion provides increased kink resistance (col. 3, line 1-20). Since the thickness in lumen wall changed, the cross sectional area and the diameter of lumen are changed also. Therefore, the given teaching of Sima'n will meet the formula above.

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Furthermore, base on the equation $F1/F2 > (D1/D2)^2$ without given any dimensions, Examiner can provide that the formula above is incorrect.

As we know the cross sectional area of circle: $F = \pi*(D/2)^2$

$F1/F2 = \pi*(D1/2)^2 / \pi*(D2/2)^2 = (D1/D2)^2$. Therefore, $F1/F2 = (D1/D2)^2$ but $F1/F2$ is not $> (D1/D2)^2$ as Applicant claimed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763